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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,184	10/18/2001	Michael A. Pellico	45191/WPC/D279	4838
23363	7590	05/20/2004	EXAMINER	
CHRISTIE, PARKER & HALE, LLP 350 WEST COLORADO BOULEVARD SUITE 500 PASADENA, CA 91105			KRASS, FREDERICK F	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 05/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/045,184

Applicant(s)

PELLICO, MICHAEL A.

Examiner

Frederick F. Krass

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/16/03; 8/11/03.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

### **Informalities**

- 1) Claim 13, fourth line, the spelling of the second term is incorrect and should be changed to --- cellulose ---.
- 2) Claims 13-16 should be amended to end in periods.

### **Indefiniteness Rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite without knowing which method of measurement was used. Honeywell Intl., Inc. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). In this instance, the "percent" values recited in claims 13-16 are indefinite since they can be calculated in a number of different ways, and no basis for their computation is set forth, e.g. percent by weight based on the total weight of the activator gel, percent by volume based on the total

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weight of the bleaching system, etc. Furthermore, the simultaneous recitation of two different weight percentages of the same "propylene glycol" component in each of the claims is confusing.

### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1) Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332).

The primary reference discloses a two-chambered syringe for tooth whitening, where the first chamber contains peroxide, and the second a basic element (col. 3, lines 47-53); the basic element contains a basic compound such as sodium hydroxide to increase its pH (col. 5, lines 19-27). The peroxide and basic element are admixed immediately prior to application (col. 3, lines 54-57), and thus are "adapted to be admixed and applied to the teeth from a dental tray for sustained contact", as required by the instant preamble. The compositions of the primary reference are preferably provided in gel form: see col. 5, lines 55-60.

The primary reference differs from the instant claims insofar as it does not specifically disclose a mixture of hydrogen peroxide and carbamide peroxide, instead teaching the use of each singly, with hydrogen peroxide being preferred. (Col. 5, lines 50-54).

The secondary reference teaches that, where it is known to use carbamide peroxide and hydrogen peroxide individually as active agents in a particular bleaching gel, it is further known to use mixtures of the two in varying concentrations to provide "bleaching compositions having a wide spectrum of bleaching agent concentrations". (Col. 5, lines 59-63). The secondary reference differs from the instant claims insofar as it is limited to one-component systems, rather than two-component systems as required instantly.

It would have been obvious to have combined the individually disclosed hydrogen and carbamide peroxides of the primary reference two-component tooth bleaching gels in varying concentrations, motivated by the desire to provide bleaching compositions having a wide spectrum of bleaching agent concentrations as taught by the secondary reference.

Regarding dependent claims 3-10, it is well-settled that normally, changes in result effective variables are not patentable where the difference involved is one of degree, not of kind; experimentation to find *workable* conditions generally involves no more than the application of routine skill in the art of chemical engineering. *In re Aller* 105 USPQ 233. Similarly, the determination of *optimal* values within a disclosed range is generally considered obvious. *In re Boesch* 205 USPQ 215. Accordingly, it would

have been obvious to one-skilled in the art, having arrived at the subject matter of instant claim 1, to have routinely tested various relative concentrations of carbamide and hydrogen peroxide to determine workable/optimal values, consonant with the reasoning of the above-cited precedent.

Regarding dependent claim 2, the primary reference teaches the use of the gelling agent hydroxyethylcellulose (col. 5, line 57), rather than hydroxypropylcellulose. It is well-settled, however, that a *prima facie* case of obviousness may be based upon structural similarity, ie. an established structural relationship between a prior art compound and the claimed compound, such as homology or position isomerization. *In re Deuel* 34 USPQ 2d at 1214; the necessary motivation to make a claimed compound, and thus the prima facie case of obviousness, rises from the reasonable expectation that compounds similar in structure will have similar properties. *In re Gyurik*, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979); *In re Grabiak* 226 USPQ 870. Accordingly, it would have been obvious to have used hydroxypropylcellulose in place of hydroxyethylcellulose as a gelling agent in the primary reference compositions, motivated by the reasonable expectation that the two compounds, which are similar in structure (related essentially as homologues), would have similar properties, consonant with the reasoning of the cited precedent.

2) Claims 1, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostler (USP 6,116,900) in view of Jensen et al (USP 5,858,332), the combination being taken further in view of Norfleet et al (USP 5,486,350).

The primary and secondary references, and the rationale for combining their teachings, are discussed in detail in subsection "1)" above. The subject matter fairly suggested by their combined teachings differs from instant claims 11 and 12 insofar as the incorporation of sodium fluoride and potassium nitrate (instant claim 11) or potassium nitrate and tetrapotassium pyrophosphate (instant claim 12) is not specified. Instant claim 1 is included in this rejection insofar as claims 11 and 12 depend therefrom.

The tertiary reference teaches that it is well-known to incorporate these additional ingredients into dentrifies. Specifically, mixtures of potassium nitrate and tetrapotassium pyrophosphate are used to reduce tooth sensitivity (col. 1, lines 9-18, for example), with sodium fluoride being used to stabilize the pyrophosphate (col. 4, lines 37-49). The tertiary reference differs from the instant claims insofar as it does not specifically disclose bleaching gels (a type of dentrifice).

It would have been obvious to have added sodium fluoride, potassium nitrate and tetrapotassium pyrophosphate to the bleaching gels suggested by the combined teachings of the primary and secondary references, motivated by the desire to increase the comfort of patients having sensitive teeth while undergoing the bleaching procedure, since those compounds are known sensitivity reducers as taught by the tertiary reference.

### **Allowable Subject Matter**

Claims 13-16 would be allowable if rewritten to include the limitations of all intervening claims, and to overcome the outstanding rejections under 35 U.S.C. 112, second paragraph.

The prior art of record does not fairly suggest, teach or disclose the particular compositions of the instant claims. The closest prior art, Ostler (USP 6,116,900), provides no direction for selecting the particular combinations of specific ingredients recited therein, let alone in the specific percentages set forth therein. Moreover, while some variation in the composition of tooth bleaching gels for the purposes of optimization might be obvious, it is well-known in the art that substantial changes can have unpredictable effects. See for example the secondary reference at col. 6, lines 30-33. To arrive at the complex mixtures recited in claims 13-16 would require more than routine experimentation/optimization, the effects of which could not be reasonably predicted from the facts of record. (Note, for example, that claims 13-16 require, *inter alia*, a mixture of thickeners, one of them being fumed silica, a species of the type (silicates) taught away from by the cited section of the secondary reference).



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### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is as follows:

Monday: 6:30-3:00PM;  
Tuesday: 10-6:30PM;  
Wednesday: off;  
Thursday: 10-6:30PM; and  
Friday: 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Seidel Marianne, can be reached on 571-272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
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